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| 10/591,062 | 10/02/2007 | Winfried Ebner | CB60766 | 5950 |
| 20462 | 7590 | 06/05/2009 | EXAMINER | |
| SMITHKLINE BEECHAM CORPORATION | | | DYE, ROBERT C | |
| CORPORATE INTELLECTUAL PROPERTY-US, UW2220 | | | | |
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| KING OF PRUSSIA, PA 19406-0939 | | | 1791 | |
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| | | | 06/05/2009 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/591,062 | EBNER ET AL. |
| | Examiner | Art Unit |
| | ROBERT DYE | 1791 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 16 March 2008.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,5,8,9 and 11 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1,5,8,9 and 11 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 8/30/2008 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

1. This Office Action is in response to Applicant's reply dated 3/16/2009 in response to a non-final Office Action. Claims 1, 5, 8, 9, and 11 have been amended and are pending. Claims 2-4, 6, 7, and 10 have been cancelled.

Specification

2. The disclosure is objected to because of the following informalities: The Specification lacks headings for the individual sections. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.

Art Unit: 1791

- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claim 1 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leversby et al. (WO 94/05183) in view of Cann et al. (USP 6,514,445), Steinebrunner (DE 10104034, already of record), Britz (US Patent 4,909,972) and Davies (WO-A-04/041025).

Art Unit: 1791

6. Regarding claim 1, Leversby et al. (hereinafter Leversby) teach a process for molding a dual component toothbrush wherein a plastic material body is provided in a first step and a second material which may be elastic (pg 4, line 24) is injection molded onto the back of plastic material head part (pg 3, lines 2-5, see figure 1, item 13, and figure 5, item 20). The mold of Leversby consists of a first and second block which forms the opposing surfaces of the brush. Although Leversby state that the material may be elastic, they do not specify that the material is a thermoplastic elastomer. In the same field of endeavor toothbrush manufacture, Cann et al. (hereinafter Cann) disclose a method for making a dual-component toothbrush head wherein a thermoplastic elastomer (col 6, line 55) is injected onto a plastic material head (col 2, lines 7-20). Cann teach that the elastomer allows the toothbrush head to be resiliently flexible (col 7, lines 62-67). Thus it would have been obvious to a person having ordinary skill in the art at the time of the invention to inject an elastomer material as taught by Cann into the mold of Leversby to provide for a toothbrush head that is resiliently flexible (col 7, lines 62-67).

7. The hypothetical combination of Leversby and Cann still do not teach that the mold is provided with a means to allow air to vent from the mold cavity other than the primary split line. In the same field of endeavor of making toothbrushes, Steinebrunner teaches a mold for making toothbrushes which includes two mold blocks for the front and back surfaces of the toothbrush and within the second block, Steinebrunner teaches a vent channel leading to the atmosphere for the purpose of preventing hot gases and molding material from entering molding channels for the bush bristles

Art Unit: 1791

(translated abstract). Thus it would have been obvious to a person having ordinary skill in the art at the time of the invention to have included a mold configuration with a means to vent air from the mold cavity as taught by Steinebrunner in the hypothetical combination of Leversby and Cann for the purpose of preventing hot gases from entering the molding channels for the brush bristles during the elastomer injection step. Steinebrunner teaches that the vent channel is located in the second mold block (second block is on the back face of the toothbrush head) (see figure 1). It would have been obvious for a person having ordinary skill in the art at the time of the invention to position the vent channel in the second mold block as taught by Steinebrunner in the invention of Leversby for the purpose of providing an unobstructed pathway for the vent channel to reach the atmosphere.

8. The combination of Leversby, Cann and Steinebrunner, does not teach a process wherein the second mold block is comprised of two parts and that the split line comprises the means to allow air to vent from the mold cavity. Britz teaches a method for molding an article in a vented mold wherein the vents are formed in the split line between two parts (col 7, lines 36-39 and figure 5) and that this split line may extend along the entire length of the mold cavity in order to promote the formation of a molded product having uniform density along its entire length (col 6, lines 14-18). Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to have used a split line as a venting means as taught by Britz to serve as the vent in the hypothetical combination of Leversby, Cann and Steinebrunner for the benefit of promoting the formation of a molded product with uniform density (col 6, lines 14-18).

9. Regarding the elastomer ribs, the aforementioned combination does not teach a method wherein the elastomer material forms ribs across the longitudinal direction of the toothbrush and extend in a height direction perpendicular to the head. In the same field of endeavor of toothbrush manufacture, Davies teaches a toothbrush wherein flaps are included on the opposite surface of a toothbrush head (see figures 1 and 12) that are preferably formed from thermoplastic elastomer material (pg 2, line 15). Davies teaches that these flaps "effect a gentler action on the oral care surfaces with massaging the buccal surfaces during regular toothbrushing or even massaging the gums as a separate action" (pg 2, lines 17-20). It would have been obvious to a person having ordinary skill in the art at the time of the invention to have included the elastomer ribs as taught by Davies in the method of Leversby, Cann, Steinebrunner and Britz for the benefit of providing the toothbrush with a means to massage the gums or scrape the tongue (pg 3, lines 27-29).

10. Regarding claim 9, Cann teaches that the elastomer is preferably injected at a temperature in the range from about 245°C to about 270°C, more preferably in the range from about 250°C to about 260°C in order to fuse the elastomer to the plastic (col 6, lines 23-26).. Thus it would have been obvious to a person having ordinary skill in the art at the time of the invention to inject an elastomer material at a temperature as taught by Cann into the mold of Leversby to provide for a toothbrush head that is resiliently flexible (col 7, lines 62-67) and to improve the strength of fusion between the elastomer and the plastic.

11. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Leversby et al. (WO 94/05183) in view of Steinebrunner (DE 10104034, already of record), Britz (US Patent 4,909,972), and Davies (WO-A-04/041025).

12. Regarding claim 5, Leversby et al. (hereinafter Leversby) teach an apparatus for molding a dual component toothbrush which comprises a mold made of a first and second mold block (see figure 5, items 26 and 27) which encloses around the head of a semi-finished toothbrush (item 2). The second mold cavity defines a cavity for the formation of part made of a second material (see item 20 in figure 5) which is formed by injection mold nozzle 33. Leversby teaches that the injection mold apparatus introduces a second material which may be elastic in the to the mold cavity. Thus it would be capable of introducing a thermoplastic elastomer material into the mold.

13. Leversby do not teach that the mold is provided with a means to allow air to vent from the mold cavity other than the primary split line. In the same field of endeavor of making toothbrushes, Steinebrunner teaches a mold for making toothbrushes which includes two mold blocks for the front and back surfaces of the toothbrush and within the second block, a vent channel leading to the atmosphere for the purpose of preventing hot gases and molding material from entering molding channels for the bush bristles (translated abstract). Thus it would have been obvious to a person having ordinary skill in the art at the time of the invention to have included a mold configuration with a means to vent air from the mold cavity as taught by Steinebrunner in the apparatus of Leversby the purpose of preventing hot gases from entering the molding

Art Unit: 1791

channels for the brush bristles during the elastomer injection step. Steinebrunner teaches that the vent channel is located in the second mold block (second block is on the back face of the toothbrush head) (see figure 1). It would have been obvious for a person having ordinary skill in the art at the time of the invention to position the vent channel in the second mold block as taught by Steinebrunner in the apparatus of Leversby for the purpose of providing an unobstructed pathway for the vent channel to reach the atmosphere.

14. The hypothetical combination of Leversby and Steinebrunner does not teach an apparatus wherein the second mold block is comprised of two parts and that the split line comprises the means to allow air to vent from the mold cavity. In the same field of endeavor of vented molds, Britz teaches an apparatus for molding an article in a vented mold wherein the vents are formed in the split line between two parts (col 7, lines 36-39 and figure 5) and that this split line may extend along the entire length of the mold cavity in order to promote the formation of a molded product having uniform density along its entire length (col 6, lines 14-18). Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to have used a split line as a venting means as taught by Britz to serve as the vent in the hypothetical combination of Leversby and Steinebrunner for the benefit of promoting the formation of a molded product with uniform density (col 6, lines 14-18).

15. Regarding the elastomer ribs, Leversby do not teach a mold cavity for forming ribs that cross the longitudinal direction of the toothbrush and extend in a height direction perpendicular to the head. In the same field of endeavor of toothbrush

Art Unit: 1791

manufacture, Davies teaches a toothbrush wherein flaps are included on the opposite surface of a toothbrush head (see figures 1 and 12) that are preferably formed from thermoplastic elastomer material (pg 2, line 15) and can be formed in an injection mold (pg4, line 31). Davies teaches that these flaps "effect a gentler action on the oral care surfaces with massaging the buccal surfaces during regular toothbrushing or even massaging the gums as a separate action" (pg 2, lines 17-20). Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to have modified the second mold of Leversby to provide it with concavities to form elastomer ribs as taught by Davies for the benefit of producing an apparatus capable of producing a toothbrush with a means to massage the gums or scrape the tongue (pg 3, lines 27-29).

16. Regarding claim 8, Leversby discloses a mold which comprises a first and second mold block which mate at a primary split line, said split line located between the first and second surfaces of the tooth brush head (see Fig. 5).

17. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Leversby et al. (WO 94/05183) in view of Cann et al. (USP 6,514,445), Steinebrunner (DE 10104034, already of record), Britz (US Patent 4,909,972) and Davies (WO-A-04/041025) as applied to claim 9 above, and further in view of Torniainen et al. (USP 6306238).

18. Regarding claim 11, the hypothetical combination of Leversby, Cann, Steinebrunner, Britz, and Davies teaches the method of making a toothbrush as applied

to claim 9. The combination does not expressly teach the temperature at which the molded part is ejected from the mold. However, it is well known in the art to allow a molded article to cool following an injection molding process so as to permit sufficient solidification of the resin. For example, Torniainen et al. (hereinafter Torniainen) discloses as prior art, a method for making a plastic part wherein hot melt plastic is fed into an injection molding machine, formed into a desired shape, cooled to about room temperature to form a solid part, and then ejected from the molding device. It would have been obvious to a person having ordinary skill in the art at the time of the invention to allow the injection molded article of Leversby to cool for the purpose of ensuring sufficient solidification and to avoid deforming of the article once ejected from the mold.

19. Regarding the specific ejection temperature of 30-40°C, although the room temperature stated By Torniainen et al. does not fall within the 30 to 40°C range, it would have been obvious to one having ordinary skill in the art to conduct limited experimentation to optimize the molding process and adjust the cooling temperature as needed, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involve only routine skill in the art. See *In re Aller*, 105 USPQ 233, 235. One would have been motivated to eject at a higher temperature for the purpose of reducing the cooling time required in the molding process while still permitting a solidified product to be ejected.

Response to Arguments

20. Applicant's arguments filed 3/16/2009 have been fully considered but they are not persuasive. The Applicant's arguments are summarized as follows:

Art Unit: 1791

- a. The vented gas of Steinebrunner exits from the primary split line and not a secondary venting channel in the second mold block
- b. The applied prior art does not provide guidance on flow problems involving the injection of an elastomer.
- c. The method and apparatus of Britz differs significantly from the process and apparatus of the claimed invention and one would not expect the teachings of Britz to be applicable.
- d. Torniainen teaches plastic and not elastomer.

21. Regarding the vent placement of Steinebrunner, the vented gas exits via channels 12 and 14 which are positioned next to the mold cavity such that the vented gas exits the cavity, enters the channels, and exits through the second mold block instead of through the primary split line which separates the two molding blocks. The vented air passes through separating strip 13 (Fig 1, abstract) to enter the vent channels.

22. In response to applicant's argument that the references fail to discuss the flow problems that might occur with the use of elastomer, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). The combination is still obvious even though neither reference recognize the advantages in the resin flow within the injection cavity.

23. In response to applicant's argument that Britz is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Britz is considered to be reasonably pertinent to the particular problem with which the applicant is concerned, namely molds which allow for the venting of gas. Britz discloses the molding of an elongate article which requires the venting of gases contained within. Britz discloses a secondary split line which extends along the elongate article to permit the release of air and to promote formation of a uniform article (col 6, lines 12-18). The hypothetical combination of Leversby, Cann and Steinebrunner also deal with a vented mold to permit gas escape. Although Britz employs a slow forming foam instead of an injection molded elastomer, the use of a vented mold to allow gas to escape is considered pertinent.

24. Although Torniainen discloses the injection molding of a plastic article instead of an elastomer, Torniainen teaches that it is known in the prior art to cool an injection molded article following the injection of molten resin for the purpose of solidifying said article to permit ejection. Such is considered to be applicable to the molding of elastomer articles. Regarding the temperature range of 30-40C, as discussed above, it is considered to be within the skill of a person having ordinary skill in the art to conduct routine experimentation to determine the cooling temperature at which an article can be safely ejected.

Conclusion

25. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Baudin (USP 5,935,620).

26. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT DYE whose telephone number is (571)270-7059. The examiner can normally be reached on Monday to Friday 8:00AM to 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph S. Del Sole can be reached on (571)272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RCD

/Joseph S. Del Sole/
Supervisory Patent Examiner, Art Unit 1791